From:	Christ, Lisa
To:	Hernandez-Quinones, Samuel
Subject:	FW: Materials for Radiation PAG Brief on May 5
Date:	Friday, May 02, 2014 2:29:23 PM
Attachments:	Brieifng for PGrevatt_SHQ 5-1_LC.docx

Hi Sam,

I spoke with Eric last night about how best to go over the equations, etc with Peter. We agreed to move it to the an appendix and we'll offer Peter a quick tutorial if he wants. If he doesn't feel he needs it we'll go straight to the briefing. I made a few other minor wording changes too.

Thanks-

Lisa

From: Christ, Lisa
Sent: Friday, May 02, 2014 2:27 PM
To: Lopez-Carbo, Maria
Cc: Hernandez-Quinones, Samuel; Ellis, Jerry; Burneson, Eric; Mason, Paula
Subject: Materials for Radiation PAG Brief on May 5

Hi Maria,

Attached are the materials for Monday's pre-brief for Peter.

Thanks and have a great weekend!

Lisa

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Briefing for Peter Grevatt
Drinking Water Radiation Protective Action Guide
May 5, 2014

Purpose:

- Seek agreement on guiding principles and assumptions for the drinking water PAG.
- Provide options for selecting a drinking water PAG.
- Seek guidance on process to solicit public comment.

Background on SDWA MCLs

- EPA Maximum Contaminant Level (**4 mrem annual dose**)
  - For I-131 in drinking water the derived concentration corresponds to **3 pCi/L**
  - Based on limiting the dose to the thyroid to 4 mrem/yr
  - Assumes 70-year (lifetime) exposure through drinking water
  - Utilizes dose calculation methods developed in 1958 (ICRP 2)
- Current science (ICRP 72) would calculate the 4 mrem effective dose to the whole body, not a specific organ
  - 55 pCi/L for Children & 120 pCi/L for Adults for I-131

Scenarios Evaluated:

EPA's contractor prepared extensive tables to evaluate multiple radiation scenarios. For example the tables assessed:

- Different event durations (i.e., 30 days, to 365 days)
- Different subpopulations, different dose levels, & different nuclides of concern

Findings from Assessment - Drinking Water PAG:

Dose (mrem)	4 mrem	25 mrem	75 mrem	100 mrem	250 mrem	500 mrem
Subpopulation Highest Risk	Infant	Infant	Infant	Infant	Infant	Infant
Projected Risk	4.67E-06	2.92E-05	8.70E-05	1.17E-04	2.92E-04	5.84E-04
Concentration (pCi/L)	84	527	1580	2110	5270	10500
Most Restrictive Concentration) (pCi/L, 5 yr old)	52	328	985	1310	3280	6570
Projected Risk	4.08E-06	2.55E-05	7.65E-05	1.02E-04	2.55E-04	5.10E-04

Basis for Dose Levels:
4 mrem = Dose for current SDWA MCL
25 mrem = Equivalent to Advisory Level issued in Japan for a 90 day exposure (Infants)
75 mrem = Proportion of the FDA food PAG attributed to drinking water

100 mrem = Internationally recognized public dose limit and the Nuclear Regulatory Commission's facility limit for the general public (ICRP 103 and NCRP 116)
250 mrem = Equivalent to Advisory Level issued in Japan for a 365 day exposure (Adults)
500 mrem = Dose Value recommended by DHS (for drinking water) & FDA (for Food)

Note: Even at a low dose level, newer dosimetry and a shorter duration (i.e., one year vs. a lifetime) will result in a PAG concentration orders of magnitude higher than our MCLs for individual nuclides.

Findings:

Exposure Duration:

For low level radiation, the risks do no vary with the duration of exposure. Assuming exposure is distributed over one year yields no difference in risk than if the exposure is 30 days.

- The one year timeframe is consistent with other intermediate phase PAGs.
- Emergency responders will not need to make assumptions about the duration of the event.
- A longer exposure duration will result in a lower allowed concentration while maintaining the desired risk level.

Water Ingestion Rates:

Ingestion rates have been incorporated from Federal Guidance Report #13, which uses mean values for consumption/intake.

- The ingestion rates in Federal Guidance 13 are consistent with ingestion rates in the EPA's Exposure Factors Handbook.
- Using mean values for consumption/intake is a departure from the current OGWDW approach of setting health based standards on higher percentiles of water consumption, 90^{th} or 95^{th} percentiles.
- Different ingestion rates for subpopulations result in different concentrations at the same risk/dose level.

Subpopulation of Concern:

Based on the calculated projections, infants and children 5 years old and younger appear to have the greatest risk from exposure to radionuclides in drinking water.

- A PAG developed to protect infants and children 5 years and younger would also be at least as protective to fetuses and developing embryos.
- Selecting a PAG that protects infants and children 5 years old and younger will be conservative in protecting other populations.

Calculated Risk Ranges:

Projected risk for excess cancer cases associated with different exposure scenarios were developed for infants, children and adults. The results from these projections of the estimated excess cases of cancer generally fall within the range of risks currently found in our DW Radionuclides Rule (10^{-4} to 10^{-6}) for all projected doses evaluated (e.g., 4 mrem to 500 mrem). This risk would be additive to the overall lifetime risk from drinking water in excess of the MCL.

There are a few exceptions where the risk levels approach the 10^{-3} for dose levels higher than 250 mrem/year.

Recommendations:

- Recommend that a "seek alternative sources of drinking water" PAG level be established based on the risk levels developed from exposure to drinking water. Other protective action (i.e. seek alternative sources of drinking water for general population) could be based on the selected risk level for the subpopulation of interest.
- Recommend that I-131 be used by EPA decision makers for assessing risks for the radiological incidents covered in the PAG manual; once the dose at the acceptable risk level is selected, the dose can be converted to a concentration for nuclides of concern.
    - It's generally the first nuclide to appear following a radiation incident and it has a high morbidity risk from exposure.
- Recommend an exposure time frame of one year to assure consistency with the other intermediate phase components of the PAG.
- Recommend establishing a "do not drink" PAG level (i.e. mrem/year) that groups infants, children 5 years and younger, and pregnant women in the same category.

Options for Soliciting Public Comment:

Separate FRN for drinking water PAG proposal:

Pros:

- ✓ More transparent and sincere solicitation of input
- ✓ Avoids confusion of interim final, proposal, and final Manual
- ✓ Allows time to do more refinements and improvements in final PAG Manual

Cons:

- ✓ Delays issuance of final PAG Manual
- ✓ Potentially pushes finalization into election cycle delays at OMB
- ✓ May confuse users about status of interim 2013 PAG Manual

Combined FRN for drinking water proposal within final PAG Manual:

Pros:

- ✓ Provides final PAG Manual sooner to users
- ✓ Avoids additional delays in OMB review
- ✓ Allows interim use of water proposal in case of an incident

Cons:

- ✓ Agency may appear less willing to take input and revise/reissue final Manual
- ✓ Still requires another round of comment adjudication and finalization if changes needed

Appendix

Background Information:

- DW Advisory issued in Japan during Fukushima for Iodine-131 was 100 Becquerel/liter for Infants and 300 Becquerel/liter for Adults (about 2700 pCi/L for Infants & 8000 pCi/L for Adults).
- OGWDW was tasked with developing a PAG (expressed as a dose value) for drinking water which will be included in the EPA PAGs Manual.

Key Terms:

Bq
One becquerel (Bq) is the amount of a radioactive material (atoms or grams) that decays at a rate of 1 disintegration per second.

Ci, pCi, and dps
A curie (Ci) is an expression of the amount of radioactivity that corresponds to that amount of radioactive material (atoms or grams) that has a decay rate of 3.7E10 disintegrations per second (dps). A picocurie (pCi) is one trillionth (i.e., 10-12) of a Ci.

Rem and mrem
A rem is an expression of the amount of ionizing radiation absorbed by tissue multiplied by the a quality factor that takes into consideration the relative potential amount of damage the radiation might cause; a mrem (millirem) is 0.001 rem.

For example, for an internally deposited radionuclide, such as Cs-137, each time an atom of Cs-137 decays inside the body, it emits a certain amount of ionizing radiation in the form of beta particles (essentially electrons) and gamma rays (i.e., energetic photons). When this energy is deposited in tissue, the molecules that comprise living tissue are ionized, which results in an increased risk of cancer. The product of the absorbed dose to tissue (which is expressed in terms of rad) with the use of a quality factor is referred to as the dose equivalent, expressed in units of rem or millirem. If 100 ergs per gram of any combination of beta particles or photons is deposited into a gram of tissue, the absorbed dose to the exposed tissue is 1 rad and the dose equivalent to that tissue is 1 rem. If the energy deposited in tissue is in due to an alpha particle, the quality factor is 20 and the dose equivalent is 20 rem because the damage caused by the energy of an alpha particle in a gram of tissue is about 20 times greater than the same amount of energy of beta and photon radiation deposited in a gram of tissue. If that energy is deposited uniformly in every gram of tissue in the body (whether alpha, beta or gamma), the exposure is defined as a whole body dose or effective dose.

Sv
A sievert (Sv) is 100 rem. Sv is the International System of Units (SI) derived unit of ionizing radiation dose (the rem and mrem are older, non-SI units).

Effective dose
When ionizing radiation is deposited in tissue, it can be deposited in only a small part of the body or uniformly throughout the body. The potential for harm associated with 1 rem (100 ergs/g) deposited in only a portion of the body is less than the potential for harm if the entire body experiences 1 rem. In order to establish risk equivalency between a partial and a whole body dose when only a portion of the body is exposed, the dose equivalent to the tissue experiencing the exposure is multiplied by a tissue weighting factor which converts the tissue dose to an effective whole body dose, or simply referred to as the effective dose.

For example, if a person ingests I-131, most of the internal dose will be delivered to the thyroid gland. The tissue weighting factor for the thyroid gland is 0.04. This means that the risk of cancer from the exposure of only the thyroid gland is about 0.04 of the risk of cancer if that same dose was delivered to the entire body. Hence, if one rem is delivered to the thyroid gland due to the ingestion of I-131, the effective whole body dose is 0.04 rem. If Cs-137 is ingested, it is distributed to the whole body so there is no need to apply a tissue weighting factor because the whole body is uniformly exposed.

DCF
Dose Conversion Factor (DCF), if a person were to ingest a given radionuclide, the radionuclide might remain in his or her body for a long time. Hence, when we refer to a dose of 500 mrem delivered due to the ingestion of contaminated water for a one year period, the actual dose is the dose delivered to that person over his or her lifetime due to the radionuclides ingested in that year. Hence 500 mrem is actually 500 mrem lifetime dose commitment.

MODELS AND ASSUMPTIONS

The fundamental equations that are used to derive trigger levels are as follows.

The effective whole body dose (mrem or Sv) due to the ingestion of radionuclide *i* to age group *a* over time period *T* is derived as follows:

$$\mathbf{D_{iaT} = I_{iaT} \times DCF_{ia}}$$

Where:

D_{iaT} = Effective whole body dose (mrem or Sv) due to the ingestion of radionuclide *i* to age group *a* over time period *T*

I_{iaT} = The total intake of radionuclide *i* for age group *a* (pCi or Bq) over time period *T*

DCF_{ia} = The effective dose coefficient (also referred to as the whole body dose conversion factor or DCF) for the ingestion of radionuclide *i* in drinking water and age group *a* (mrem/Bq or Sv/Bq) using the DCFs from FGR-13.

Risk is expressed in terms of total cancer risk (morbidity) as opposed to fatal cancer risk (i.e., mortality). The lifetime risk of cancer due to the ingestion of radionuclide *i* by age group *a*.:

$$\mathbf{R_{iaT} = I_{iaT} \times RC_{ia}}$$

Where:

R_{iaT} = The lifetime risk of cancer due to the ingestion of radionuclide *i* over time period *T* by age group *a* (life risk of cancer per Bq or per pCi ingested).

I_{iaT} = The total intake of radionuclide *i* for age group *a* (pCi or Bq) over time period *T*.

RC_{ia} = The lifetime risk coefficient for the ingestion of radionuclide *i* in drinking water and age group *a* [lifetime risk per pCi (or per Bq) ingested in water] using the RCs from FGR-13.

To derive the quantity of radionuclide *i* ingested by age group *a* over a given time period, *T*.

$$\mathbf{I_{iaT} = C_i \times Ing_a \times T}$$

Where:

I_{iaT} = The total intake of radionuclide *i* for age group *a* (pCi or Bq) over time period *T* (days)

C_i = The concentration of radionuclide *i* in drinking water (pCi/L or Bq/L). In this analysis, the concentration of the radionuclide is assumed to be constant over the time period *T* of interest.

Ing_a = The daily ingestion rate of water for age group *a* as provided in FGR-13 (L/day).

T = The time period that the population is drinking contaminated water (days

Dose Conversion Factors

DCFs (Sv per Bq ingested at the age indicated)

Isotope	DCFs from FGR-13*			
	Infant (100 day old)	1 year old	5 year old	Adult
Cs-137	2.11E-08	1.24E-08	9.69E-09	1.36E-08
I-131	1.84E-07	1.79E-07	1.04E-07	2.18E-08

Lifetime Morbidity Risk Conversion Factors

(per Bq ingested in water at the indicated age)

Isotope	Infant	1 yr old	5 yr old	Adult (age 25-70)
Cs-137	3.40E-09	2.49E-09	1.97E-09	6.17E-10
I-131	2.15E-08	1.99E-08	1.06E-08	4.58E-10

Drinking Water Ingestion Rates from FGR-13

Age (years)	Tap Water (L/day)*	
	Male	Female
0	0.191	0.188
1	0.223	0.216
5	0.542	0.499
20	1.137	0.754
50	1.643	1.119